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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/005,753

10/29/2001

Yasuhiro Sakai

3029-74

7298

7590

11/22/2005

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,753

Applicant(s)

SAKAI ET AL.

Examiner

Francisco C. Prats

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22-27 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 and 31 is/are allowed.
- 6) ☒ Claim(s) 20,22-24,26 and 27 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed September 15, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 20, 22-27 and 30-32 are pending.

Election/Restrictions

Applicant's election of the species wherein the nitrite reducer is sulfamic acid, in Paper No. 5, filed June 9, 2003, is again acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Because a composition as recited in claim 20, comprising

(a) a polymethine dye,

(b) a nitrite reducer selected from the group consisting of sulfamic acid or isoascorbic acid, and

(c) a buffer for maintaining an acidic pH,
is considered free of the prior art, the search has been extended to additional species recited within the Markush group recited in claim 20. See MPEP § 803.02.

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Newly submitted claim 32 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 32 is directed to a staining composition comprising one of 9 specifically named buffers, none of which were presented with the originally filed claims.

As discussed above, applicant has received an action on the merits for the originally presented invention directed to a staining composition comprising:

- (a) a polymethine dye,
- (b) a nitrite reducer selected from the group consisting of sulfamic acid or isoascorbic acid, and
- (c) **any** buffer for maintaining an acidic pH.

Thus, that invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 32 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

As noted above, examination has been extended to other species within the Markush group now in amended claim 20.

Claims 20, 22-27, 30 and 31 are examined on the merits.

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Claim Rejections - 35 USC § 103

Claims 20, 22-24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizukami et al (EP 0 882 983 A2) in view of Janoff et al (U.S. Pat. 5,578,320) or Dickhardt et al (U.S. Pat 5,245,008).

Mizukami discloses processes whereby a reagent comprising a polymethine dye and a quaternary ammonium surfactant, at a pH ranging from 4.5 to 11, is used to differentially stain leukocytes. See pages 3 and 4. Mizukami differs from the claims in failing to disclose the inclusion in the reagent of a substance capable of reducing nitrite ions.

However, Mizukami clearly discloses the desirability of using a buffer in the composition. See, e.g., page 4, lines 32-34, disclosing the use of various buffers, including the organic acid citric acid. Thus, one of ordinary skill in the art at the time of applicant's invention clearly would have recognized that the claim-recited compound glutamic acid, also a well known organic acid known to be suitable for use as a buffer within the pH range (4.5 to 11), would have been suitable for use as a buffer in Mizukami's compositions.

For example, each of Janoff (column 13, lines 13-20; pH of 5.5 and 7.5 used in process of dehydrating liposomes) and Dickhardt (column 8, lines 17-24; pH 5.5 used in insulin

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purification) clearly discloses the suitability of glutamic acid as a buffer for use in applications requiring the maintenance of biological activities. Recognizing from Janoff and Dickhardt the suitability of glutamic acid as a buffer in processes wherein biological activities are preserved, the artisan of ordinary skill would have been motivated to have included it in Mizukami's staining reagent as the buffering component. Thus, the artisan of ordinary skill would have been motivated to have included a compound which meets the claim limitations of being both a buffer for maintaining an acidic pH, and being a nitrite ion reducer. A holding of obviousness over the cited claims is therefore required.

Claims 30 and 31 are allowed. Claim 25 is objected to as depending from a rejected claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this

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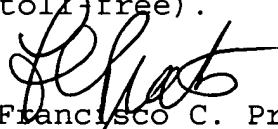
action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).


Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP